

Clean Version of all Pending Claims Pursuant to 37 C.F.R. §1.121**WHAT IS CLAIMED IS:**

19. An article of manufacture comprising packaging material and a pharmaceutical agent contained within said packaging material, wherein said pharmaceutical agent is effective for treating premature ejaculation in a human male, and wherein said packaging material comprises a label which indicates that said pharmaceutical agent can be used for treating premature ejaculation in a human male on an as-needed basis prior to a sexual activity, and wherein said pharmaceutical agent comprises a rapid-onset selective serotonin reuptake inhibitor or a pharmaceutically acceptable salt thereof.

20. An article of manufacture comprising packaging material and a pharmaceutical agent contained within said packaging material, wherein said pharmaceutical agent is effective for treating premature ejaculation in a human male, and wherein said packaging material comprises a label which indicates that said pharmaceutical agent can be used for treating premature ejaculation in a human male on an as-needed basis prior to a sexual activity, and wherein said pharmaceutical agent comprises dapoxetine or a pharmaceutically acceptable salt thereof.

21. (Amended) An article of manufacture comprising packaging material and a pharmaceutical agent contained within said packaging material, wherein said pharmaceutical agent is effective for treating premature ejaculation in a human male, and wherein said packaging material comprises a label which indicates that said pharmaceutical agent can be used for treating premature ejaculation in a human male on an as-needed basis prior to a sexual activity, and wherein said pharmaceutical agent comprises dapoxetine or a pharmaceutically acceptable salt thereof, and wherein the label indicates that the dapoxetine is to be administered about immediately prior to, to about 4 hours prior to a sexual activity.

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22. An article of manufacture according to claim 20 wherein the label indicates that dapoxetine is to be administered immediately prior to, to about 3 hours prior to a sexual activity.

23. An article of manufacture according to claim 20 wherein the label indicates that dapoxetine is to be administered immediately prior to a sexual activity.

24. A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of a rapid-onset selective serotonin reuptake inhibitor.

25. The method of claim 24, wherein the mammal is a human male.

26. The method according to claim 25 wherein the sexual dysfunction is selected from the group consisting of premature ejaculation, retarded ejaculation, low sexual desire, sexual aversion, or inhibited orgasm.

27. (Amended) A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of a rapid-onset selective serotonin reuptake inhibitor, wherein the sexual dysfunction is premature ejaculation and the mammal is a human male.

28. The method of claim 27, wherein the as-needed basis is about 1 hour to about 8 hours prior to a sexual activity.

31. (Amended) A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of a rapid-onset selective serotonin reuptake inhibitor, wherein said rapid-onset selective serotonin reuptake inhibitor is short acting.

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32. (Amended) A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of a rapid-onset selective serotonin reuptake inhibitor, wherein said rapid-onset selective serotonin reuptake inhibitor is delivered in a rapid release formulation.

34. A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof.

35. The method of claim 34, wherein the mammal is a human male.

36. The method of claim 35, wherein the sexual dysfunction is selected from the group consisting of premature ejaculation, retarded ejaculation, low sexual desire, sexual aversion, or inhibited orgasm.

37. (Amended) A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof, wherein the sexual dysfunction is premature ejaculation and the mammal is a human male.

38. The method of claim 37, wherein dapoxetine is administered immediately prior to, to about 12 hours prior to a sexual activity.

39. The method of claim 37, wherein dapoxetine is administered immediately prior to, to about 8 hours prior to a sexual activity.

40. (Amended) A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to th

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mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof, wherein the sexual dysfunction is premature ejaculation, wherein the mammal is a human male, and wherein dapoxetine is administered immediately prior to, to about 4 hours prior to a sexual activity.

41. The method of claim 37, wherein dapoxetine is administered immediately prior to, to about 3 hours prior to a sexual activity.

42. The method of claim 37, wherein dapoxetine is administered immediately prior to a sexual activity.

43. The method of claim 24, further comprising administering a therapeutically effective amount of an additional therapeutic agent for treating or managing a second, different sexual dysfunction.

44. The method of claim 34, further comprising administering a therapeutically effective amount of an additional therapeutic agent for treating or managing a second, different sexual dysfunction.

45. The method of claim 34, wherein the therapeutically effective amount of dapoxetine or its pharmaceutically acceptable salt is from about 0.01 mg to about 200 mg.

46. (Amended) A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof, wherein the therapeutically effective amount of dapoxetine or its pharmaceutically acceptable salt is from about 0.1 mg to about 120 mg.

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47. The method of claim 46, wherein dapoxetine or its pharmaceutically acceptable salt is administered orally.

48. The method of claim 47, wherein dapoxetine or its pharmaceutically acceptable salt is administered in an oral solid dosage form.

49. The method of claim 48, wherein dapoxetine or its pharmaceutically acceptable salt is administered as a tablet or a capsule.

50. (Amended) A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof, wherein dapoxetine or its pharmaceutically acceptable salt is delivered as a rapid release formulation.

51. A method of treating premature ejaculation in a human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof immediately prior to, to about 4 hours prior to a sexual activity.

52. A method of treating premature ejaculation in a human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof immediately prior to, to about 3 hours prior to a sexual activity.

53. A method of treating premature ejaculation in a human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof about 30 minutes to about 3 hours prior to a sexual activity.

54. A method of treating premature ejaculation in a human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of

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dapoxetine or a pharmaceutically acceptable salt thereof immediately prior to a sexual activity.

55. (New) The method according to claim 34 wherein the therapeutically effective amount of dapoxetine is from about 0.001 mg to about 350 mg.

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